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Health Centers, Ryan White Clinics
for 340B Access, Little Rivers Health
Care, Inc., and WomenCare, Inc.,
dba FamilyCare Health Center*

NOVO NORDISK INC. et al,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 3:21-cv-00806-FLW-LHG

**UNOPPOSED MOTION TO FILE AMICUS CURIAE BRIEF IN SUPPORT
OF DEFENDANTS' MOTION TO DISMISS AND FOR SUMMARY
JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' CROSS MOTION
FOR SUMMARY JUDGMENT**

The National Association of Community Health Centers ("NACHC"), Ryan White Clinics for 340B Access ("RWC-340B"), Little Rivers Health Care, Inc. ("Little Rivers"), and WomenCare, Inc., dba FamilyCare Health Center ("FamilyCare") (collectively the "Amici"), by and through undersigned counsel, respectfully request leave to file a brief as amici curiae in the above-captioned case. Amici's brief will support Defendants' Motion to Dismiss and for Summary Judgment and oppose the Plaintiffs' Cross Motion for Summary Judgment. Defs.' Mem. in Supp. of Defs.' Mot. to Dismiss, or, in the Alternative, for Summ. J., ECF

No. 37-1 (“Defs.’ MTD”); Pls.’ Combined Mem. in Supp. of Cross-Mot. for Summ. J. and in Opp’n to Defs.’ Mot. to Dismiss or, in the Alternative, for Summ. J., ECF No. 45-1 (“Pls.’ MSJ”). Amici have conferred with counsel to the Parties regarding this motion. Defendants consent to Amici’s participation. Plaintiffs take no position at this time on Amici’s motion and reserve the right to respond to this motion.

Amici have a significant interest in the outcome of this litigation and request the opportunity to inform the Court about the impact that its decision will have on Amici’s safety-net operations and patients. The Amici’s brief focuses on the harms that dispositive rulings against Defendants and for Plaintiffs will cause to community-based 340B covered entities and their vulnerable patients. This Court has “broad discretion” to determine the “extent, if any, to which an amicus curiae should be permitted to participate in a pending action.” *Bryant v. N.J. Dep’t of Transp.*, 987 F. Supp. 343, 346 n. 3 (D.N.J. 1998) (*rev’d on other grounds*); *see also Yip v. Pagano*, 606 F. Supp. 1566, 1568 (D.N.J. 1985), *aff’d*, 782 F.2d 1033 (3d Cir. 1986). Amici’s motion should be granted for several reasons: (1) the Amici have a “special interest” in this case; (2) the Amici’s interest is not represented adequately or at all in the case; and (3) the proffered information is

timely and useful.¹ *United States v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002). The Amici meet all three criteria to be granted leave to file an *amicus curiae* brief.

First, the Amici have a special interest in this case because the Amici's covered entity members rely heavily on the 340B contract pharmacy program to serve their vulnerable patients. *See Alkaabi*, 223 F. Supp. 2d at 592. NACHC, founded in 1971, is a nonprofit organization with a national membership of federally-funded clinics, known as federally-qualified health centers ("FQHCs"). FQHCs provide crucial primary health care and related services in all fifty states and the District of Columbia and in Puerto Rico and other U.S. territories, regardless of patient insurance status or ability to pay for such services; approximately one in twelve Americans receive care at an FQHC. NACHC is dedicated to furthering the safety-net mission and purpose of FQHCs, and does so through extensive education, training, and advocacy, including legal representation through its associational standing and as *amicus curiae*. *See, e.g., Cal. Ass'n of Rural Health Clinics v. Douglas*, 738 F.3d 1007 (9th Cir. 2013) (concerning scope

¹ The *Alkaabi* court also examined whether the amicus was partial to a particular outcome in the case, *Alkaabi*, 223 F. Supp. 2d at 592, but this factor is not controlling. The Third Circuit has held that a party seeking to file an amicus brief does not need to be impartial and may have an interest in the outcome of the case. *Neonatology Associates, P.A. v. C.I.R.*, 293 F.3d 128, 131 (3d Cir. 2002) ("Thus, an amicus who makes a strong but responsible presentation in support of a party can truly serve as the court's friend."). Additionally, the New Jersey District Court has granted motions to file amicus briefs when the amicus was interested in the outcome of the case. *See Acra Turf Club, LLC v. Zanzuccki*, No. 12-2775, 2014 WL 5465870, at *6 (D.N.J. 2014).

of mandatory FQHC services and associated reimbursement rights in Medicaid).

FQHCs receive, or are eligible to receive, federal grant funding under Section 330 of the Public Health Service (“PHS”) Act to serve four general patient populations: residents of federally-designated medically underserved areas; homeless populations; migrant and seasonal farmworkers; and residents of public housing. 42 U.S.C. § 254b(a)(1). FQHCs provide comprehensive primary care to approximately one in twelve Americans who fall into one or more of these categories and serve on the front lines in preventing, treating, and containing serious, nationwide public health threats such as the HIV epidemic, the opioid addiction crisis, and the ongoing COVID-19 pandemic. Eighty-two percent of FQHC patients are either publicly insured (e.g., Medicare and Medicaid beneficiaries) or lack health insurance entirely. *See* NACHC, *Community Health Center Chartbook 2020* (Jan. 2020), Figs. 1-5.² For decades, FQHCs have relied on 340B Program savings and revenue to meet the needs of their vulnerable patient populations, which in 2020 included approximately one in three people living in poverty, one in five residents of rural areas, one in nine children, one in eight people of a racial or ethnic minority, and one in six Medicaid beneficiaries. *See Id.*, Figs. 1-1.

² <https://www.nachc.org/research-and-data/research-fact-sheets-and-infographics/chartbook-2020-final/> (hereinafter “NACHC Chartbook”) (last visited June 29, 2021).

RWC-340B is a national, not-for-profit association of clinics that receive funding under the Ryan White Comprehensive AIDS Resources Emergency Act (“Ryan White CARE Act”), Pub. L. No. 101-381, 104 Stat. 576 (codified at 42 U.S.C. §§ 300ff–300ff-140), to provide health care and related support services to individuals living with human immunodeficiency virus/acquired immunodeficiency syndrome (“HIV/AIDS”). Receipt of this funding qualifies the members of RWC-340B to participate in the 340B program as “covered entities” and thereby purchase outpatient drugs at discounted prices. Clinics funded under the Ryan White CARE Act provide primary medical care, medications, and support services to over half a million underserved and uninsured individuals living with HIV/AIDS. RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction*, 2–3 (Oct. 2020).³ Ryan White clinic patients are “more likely to have less than a high school education, live in poverty, and be homeless” than people living with HIV/AIDS who are not treated in Ryan White clinics. *Id.* at 6. Nevertheless, Ryan White clinic patients are more likely to achieve HIV viral suppression than patients seen elsewhere. *Id.* at 4.

RWC-340B has members in all regions of the United States, including members that operate at least nine clinics throughout New Jersey. RWC-340B’s

³ <https://www.rwc340b.org/wp-content/uploads/2020/10/20200921-RWC340B-White-Paper-FINAL.pdf> (last visited June 29, 2021).

members are typically small, nonprofit organizations that do not have the financial resources to operate in-house pharmacies and instead participate in the 340B Program by ordering drugs for shipment to contract pharmacies, which dispense the drugs to the members' patients. For many Ryan White clinics, contract pharmacy arrangements are the primary, or even sole, path to 340B discounts and revenue, a funding source on which these clinics have long relied. Seventy-five percent of Ryan White clinics have contract pharmacy arrangements. *See* Health Resources and Services Administration ("HRSA"), *Welcome to 340B OPAIS*, <https://340bopais.hrsa.gov/> (last visited June 29, 2021).

Little Rivers is a not-for-profit health care provider with facilities located in Wells River, Bradford, and East Corinth, Vermont. Little Rivers' mission is to provide respectful, comprehensive primary health care for all residents in its region, regardless of ability to pay. Little Rivers is certified by the Department of Health and Human Services ("HHS") as an FQHC, which qualifies Little Rivers to participate as a covered entity in the 340B program. Little Rivers has been registered as a covered entity in the 340B program since 2006. Statistics from HRSA, the division of HHS that administers FQHC grants, show that Little Rivers served more than 5,500 patients in 2019 and that, of those patients with known incomes, 61.2% had income at or below 200% of the Federal Poverty Level ("FPL"), including 19.48% with income at or below 100% of the FPL. HRSA,

*Health Center Program Data for Little Rivers, Patient Characteristics.*⁴ In 2019, approximately 50% of Little Rivers' patients were either Medicaid or Medicare recipients and approximately 5% of its patients were uninsured. *Id.* Little Rivers does not operate an in-house pharmacy and participates in the 340B program by using contract pharmacy relationships.

FamilyCare is a not-for-profit health care provider with several facilities in West Virginia, including three mobile units and clinics at local schools.

FamilyCare's mission is to make high-quality, whole-person care available to every member of the family and every member of the community. FamilyCare is an FQHC and is eligible to participate as a covered entity in the 340B program by virtue of that designation. FamilyCare has been registered as a covered entity in the 340B program since 2000. According to HRSA statistics, FamilyCare served 32,353 patients in 2019, and of those patients with known incomes, 99.53% have annual incomes at or below 200% of the FPL, including 50.43% with annual incomes at or below 100% of the FPL. HRSA, *Health Center Program Data for WomenCare, Patient Statistics.*⁵ In 2019, approximately 63% of FamilyCare's patients were either Medicaid or Medicare recipients and 7.46% of its patients were uninsured. *Id.* FamilyCare does not operate an in-house pharmacy and

⁴ <https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658> (last visited June 29, 2021).

⁵ <https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS00827> (last visited June 21, 2021).

participates in the 340B program by using contract pharmacy relationships.

Amici also have a special interest in this case because they have direct interests in other cases that may be materially affected by the Court's decision in the instant action. *Alkaabi*, 223 F. Supp. 2d at 592. All of the Amici are plaintiffs in lawsuits against several of the Defendants that seek to enforce the rights of covered entities to obtain 340B discounts through contract pharmacies. Amended Compl., *RWC-340B*, ECF No. 21 (stayed Jan. 13, 2021); Compl., *NACHC*, (D.D.C. Oct. 21, 2020), ECF No. 1 (stayed Jan 7, 2021). The Defendants' Memorandum to Support Its Motion to Dismiss and Motion for Summary Judgment provides some of the factual background for these actions by Amici. Defs.' MTD at 7, ECF No. 37-1 ("During the latter half of 2020 several drug makers took abrupt, unilateral actions to restrict access to their drugs by covered entities that rely on contract pharmacies to take delivery of, and dispense, medications to low-income patients.").

The Amici's interest in the 340B contract pharmacy program stems from their missions to provide critical safety-net services to vulnerable communities. The future of the contract pharmacy program will affect the Amici's ability to continue to provide services to these communities, to provide discounted drugs to indigent patients, and to offer pharmacy services throughout their service areas for patients who cannot travel vast distances to obtain vital, life- sustaining

medications.

When manufacturers stopped shipping 340B discounted drugs to Amici's contract pharmacies, their options to vindicate their rights were limited in important ways. First, covered entities are precluded from bringing an action directly against a drug manufacturer to enforce the 340B statute. *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110 (2011). Second, Congress had ordered HHS to implement an alternative dispute resolution ("ADR") process to resolve disputes between covered entities and manufacturers, but HHS had not yet adopted final ADR regulations. Therefore, the Amici's only recourse was to file suit against several of the Defendants to seek an order directing them to promulgate ADR regulations or to otherwise remedy the manufacturers' actions. HHS subsequently issued the ADR regulations. 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020).

On January 7, 2021, the D.C. District Court in *NACHC v. Azar* stayed the case to allow Amici NACHC to pursue ADR claims against drug manufacturers, and on January 13, 2021, the court in *RWC-340B v. Azar* did the same. Joint Mot. to Stay, *NACHC*, (D.D.C. Oct. 21, 2020), ECF No. 12; Joint Mot. to Stay, *RWC-340B*, ECF No. 58. Amici NACHC, Little Rivers, and FamilyCare have already filed ADR Petitions. In addition, the United States District Court for the Northern

District of California recently ruled that that the 340B statute requires that disputes between covered entities and manufacturers must first be adjudicated through the ADR process. *Am. Hosp. Ass'n v. Dep't of Health & Human Servs.*, No. 4:20-CV-08806-YGR, 2021 WL 616323 (N.D. Cal. Feb. 17, 2021), ECF No. 91. Both *NACHC v. Azar* and *RWC-340B v. Azar* continue to be stayed, pending the outcome of the ADR proceedings (or action by the Defendants that would resolve the disputes for which the Amici filed ADR petitions). *NACHC*, Joint Status Report, ECF No. 15; *RWC-340B*, Joint Status Report, ECF No. 63.

Second, the Amici are not adequately represented in this case. *See Alkaabi*, 223 F. Supp. 2d at 592. Clearly, Plaintiffs do not represent Amici's interests because Plaintiffs challenge the contract pharmacy program upon which Amici rely. Defendants also do not adequately represent Amici's interest. Defendants administer the 340B program but are not covered entities on the front lines of furnishing health care to the disadvantaged. While Amici support the Defendants' motion to dismiss and for summary judgment, Amici are currently plaintiffs in lawsuits against several of the Defendants concerning both the enforcement of their rights to obtain 340B discounted drugs through contract pharmacies. Amended Compl., *RWC-340B v Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 21, (stayed Jan. 13, 2021) ("*RWC-340B*"); Compl., *NACHC v. Azar*, No. 1:20-cv-03032 (D.D.C. Oct. 21, 2020), ECF No. 1 (stayed Jan 7, 2021) ("*NACHC*").

Third, the Amici can provide the Court with useful and unique information in the instant case, and that information is timely. *Alkaabi*, 223 F. Supp. 2d at 592. Congress intended the 340B program to allow covered entities to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. Rep. No. 102-384(II), at 12 (1992); *see also Cares Cmty Health v. U.S. Dep’t of Health & Human Servs.*, 944 F.3d 950, 955 (D.C. Cir. 2019) (340B savings “help safety-net providers fund the uncompensated care they supply and expand the services they offer.”). Neither Plaintiffs nor Defendants are 340B covered entities. The Amici can, therefore, provide the Court with the perspective of the entities that the 340B program was intended to benefit, a perspective which neither Plaintiffs nor Defendants can possibly have because they are not 340B covered entities.

This motion and the attached Amicus Curiae brief are also timely. The Amici are supporting Defendants’ motion for summary judgment and opposing Plaintiffs’ cross-motion for summary judgment. Defendants filed their opposition/reply brief on June 22, 2021. ECF No. 53. Amici filed this motion with attached amicus curiae one week after Defendants’ June 22, 2021, brief. On July 6, 2021, Plaintiffs will have an opportunity in their reply brief to respond to Amici’s brief. ECF No. 35.

Therefore, the Amici respectfully move the Court for leave to file the

attached amici curiae brief and accompanying exhibits.

Respectfully submitted,

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* *Pro Hac Vice applications forthcoming*